

### § 520.813

(d) *Conditions of use*—(1) *Amount*. 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use*. Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations*. Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 3444, Jan. 24, 1989, as amended at 55 FR 43327, Oct. 29, 1990; 62 FR 38906, July 21, 1997; 64 FR 48295, Sept. 3, 1999]

### § 520.813 Enrofloxacin oral solution.

(a) *Specifications*. Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.228 of this chapter.

(d) *Conditions of use*. It is used in drinking water as follows:

(i) *Chickens and turkeys*—(i) *Amount*. 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications*. Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations*. Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 56893, Nov. 5, 1996]

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### § 520.816 Epsiprantel tablets.

(a) *Specifications*. Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 2.5 milligrams per pound of body weight.

(ii) *Indications for use*. Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(2) *Cats*—(i) *Amount*. 1.25 milligrams per pound of body weight.

(ii) *Indications for use*. Removal of feline cestodes *D. caninum* and *T. taeniaeformis*.

(3) *Limitations*. For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

### § 520.823 Erythromycin phosphate.

(a) *Specifications*. Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.230 of this chapter.

(d) *Conditions of use*. It is used in drinking water as follows:

(1) *Broiler and replacement chickens*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations*. Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3

days should not be used; withdraw 1 day before slaughter.

(2) *Replacement chickens and chicken breeders*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of infectious coryza due to *Hemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations*. Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) *Growing turkeys*—(i) *Amount*. 0.500 gram per gallon.

(ii) *Indications for use*. As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations*. Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003]

#### § 520.863 Ethylisobutrazine hydrochloride tablets.

(a) *Specifications*. Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is administered orally to dogs as a tranquilizer.<sup>1</sup>

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.<sup>1</sup>

(3) It is not to be used in conjunction with organophosphates and/or procaine

hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

#### § 520.870 Etodolac.

(a) *Specifications*. Each tablet contains 150, 300, or 500 milligrams (mg) of etodolac.

(b) *Sponsor*. See 053501 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 10 to 15 mg per kilogram (4.5 to 6.8 mg/pound) of body weight per day.

(ii) *Indications for use*. For the management of pain and inflammation associated with osteoarthritis in dogs.

(iii) *Limitations*. Use once-a-day. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 51300, Sept. 25, 1998, as amended at 68 FR 51705, Aug. 28, 2003]

#### § 520.903 Febantel oral dosage forms.

##### § 520.903a Febantel paste.

(a) *Chemical name*. Dimethyl [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl] carbonimidoyl]bis [carbamate].

(b) *Specifications*. The drug is a paste containing 45.5 percent febantel.

(c) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(d) *Conditions of use*—(1) *Amount*. Six milligrams per kilogram (2.73 milligrams per pound) of body weight in horses.

(2) *Indications for use*. For removal of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); ascarids (*Parascaris equorum*— sexually mature and immature); pinworms (*Oxyuris equi*— adult and 4th stage larva); and the various small strongyles in horses, foals, and ponies.

(3) *Limitations*. (i) The paste may be administered on the base of the tongue or well mixed into a portion of the normal grain ration.

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.